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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,417

03/01/2004

Charles A. Mesko

MESK-30

1471

26875 7590 02/09/2009
WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

02/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/790,417	Applicant(s) MESKO, CHARLES A.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,7,9-19,24,27,28,30,33 and 36-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5,7,9-19,24,27,28,30,33 and 36-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The response filed on **10/29/08** has been entered.
2. Applicant's arguments filed 10/29/08 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 4-5, 7, 9-19, 24, 27-28, 30, 33, 36-62 are pending in this office action.
5. The objection of claim 7 is withdrawn due to the amendment of the claim.
6. The rejection of claims 4-5, 7, 13, 24, 27-28 and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn due to the amendment of the claims.
7. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and recites the limitation "first ingredient is Tribulus L. terrestris and "said composition". There is insufficient antecedent basis for this limitation in base claim 4 because "the first ingredient" in claim 4 is alternatively Eurycoma longifolia jack". Additionally, different compositions are therefore recited in claims 4 & 7; thereby, being ambiguous as to which composition is actually being referenced.

Likewise, claim 19 recites "said composition" in which it is unclear which of the multiple compositions referenced in this claims and its base claim is being referred to.

Lastly, claim 36 recites the limitation "first ingredient is Cnidium monnier". There is insufficient antecedent basis for this limitation in claim 36 because the "first ingredient" in base claim 33 is "coumarin"; thereby, further being indefinite.

9. Claim 17 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reason made of record and as follows in Paper No. 20080529 and as follows. This is a written description requirement.

The claim recites a third ingredient for stimulating an increase in blood flow, the third ingredient being provided in homeopathic form. The scope of the claims includes undefined/undescribed third ingredients effective to stimulate an increase in blood flow,

and being in homeopathic form. The recitation of a very broad genus with no correlation between structure and function that identify members of the genus have not been provided. Therefore, Applicant was not in possession of the claimed genus. Thus, Applicant's argument is not persuasive and the amendment to claim 17 is insufficient to overcome the rejection.

10. Claims 4-5, 7-11, 12-19, 22, 24, 27-28, 30, 33 and 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al., (US 5,595,970) and Ang et al. (2001) and Chwalisz et al., (US 5,906,987) and Coral-Cure www.coral-cure.com/mens-health in view of Chen et al. (2002) and Chiou et al. (2001), for the reasons made of record in Paper No: 20080529, and as follows.

Applicant argues that Garfield teaches away from Ang such that any addition of *Eurycoma longifolia* jack (ELJ) to the composition is unnecessary due to the other ingredients in the composition of Garfield.

This is found not persuasive because it is *prima facie* obviousness to select a known material based on its suitability for its intended use. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964).

Next, Applicant argues that Chiou teaches the vasorelaxing effect of coumarin from *Cnidium monnieri*, and that Chiou does not teach a vesicle operable for transporting the

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first ingredient. Applicant particularly asserts that knowledge of the Cnidium monnieri of Chiou via the vesicle of Chen would not be obvious.

This is found not persuasive, as taught by Chen when applying medication to the skin one has to consider its delivery mechanism to the blood system. Chen specifically teaches phosphatidyl choline (the vesicle carrier). Chen et. al. teach topical application, as recited in current claims 24 and 33, as a means of elevating plasma concentration of dehydroepiandrosterone to treat erectile function (see page 1039, last para, left col.). Also as evidenced by Cilurzo (WO/2000/021582), coumarin has been administered transdermally in the prior art because of its known poor oral absorption (see page 3, lines 9-20 and entire reference). Therefore Chiou does not teach away from the claimed invention. One of ordinary skill in the art would have been motivated to add a known compound for the treatment of penile erection to Chiou because Chiou teaches specifically that these transdermal patches are employed for the treatment of erectile dysfunction (page 1039, left col, last para.). See also argument supra for reasons to combine known agents for the same purpose.

The argument that Chiou does not teach how the coumarins are delivered is found not persuasive because prior to Applicants claimed invention, as evidenced by Cilurzo, coumarins have been administered transdermally. The reasons given on page 22 of the remarks as to why coumarin would be delivered via ingestion and not transdermally is found not persuasive because the recited limitation is to transdermal and not to oral administration, (i.e. as it relates to claims 24 and 33) and as evidenced by Cilurzo, transdermal patches are well known in the art.

The declaration is considered and is discussed below.

11. Claims 37-60, and new claims 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al., (US 5,595,970) taken with Ang et al. (2001) and Chwalisz et al., US (5,906,987) and Coral-Cure www.coral-cure.com/mens-health in view of Chen et al. (2002), and Chiou et al. (2001) and further in view of Mesko (US 6,340,474) and McCoy et (2002), for the reasons made of record in Paper No: 20080529, and as follows. Note new claims 61 & 62 do not change the scope of the rejection.

Applicant argues that Garfield teaches away from Mckoy such that any addition of Morinda citrifolia (MC) to the composition is unnecessary. The above argument is also applied here. This is found not persuasive because it is *prima facie* obviousness to select a known material based on its suitability for its intended use. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964).

As to the statement that MC mimics certain effects of increased testosterone and would thereby reduce sexual function is found not persuasive because characteristics of a compound cannot be stripped away. See MPEP 2112.01.

Nevertheless, McCoy et al teach Morinda Citrifolia is used to treat sexual dysfunction. In particular, as to the second ingredient Morinda Citrifolia, it is also known in the art that Morinda Citrifolia is used to treat sexual dysfunction; therefore it is within the purview of one of ordinary skill in the art to add another agent that will enhance the overall activity of the composition when administered for the same treatment. Thus, Applicant's assertion that adding two or more agents to the formulation of Garfield is teaching away, is not persuasive; absent evidence to the contrary, which Applicant has not provided.

12. Declaration

The declaration under 37 CFR 1.132 filed 10/29/08 is insufficient to overcome the rejection of claims 4-5, 7, 9-19, 24, 27-28, 30, 33 and 36-62 based upon the prior art references as set forth in the last Office action because:

Applicants Declaration under 37 C.F.R. 1.132 executed by Charles A. Mesko supports and provides evidence that Chiou is a study of four coumarin on penile erectile tissue and that Chiou does not teach or include in its teaching of how to deliver coumarin to a living object. That existing drugs of erectile dysfunction are ingested not administered transdermally and therefore teaches away.

Declarant Mesko also asserts that there are reasons why coumarin would be delivered via ingestion, and those of ordinary skill would not transdermally deliver compositions transdermally.

In response, as discussed above, it is common for one of ordinary skill in the art to add agents known to be used for the same purpose to additively or synergistically enhance the treatment condition and or the composition (see supra). Per the discussion above, administering coumarin transdermally is not novel, therefore one of ordinary skill in the art would have been motivated to formulate a composition for the treatment of erectile dysfunction directly to the penis for a quicker response especially because methods of treating penile dysfunction via administration transdermally is known in the art. Lastly, this is a rejection under 35 USC 103, not a 35 USC 102.

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
1/29/08

/Robert C. Hayes/
Primary Examiner, Art Unit 1649